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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,354

09/11/2003

Gena Perlov

1023/13

5554

7590

02/25/2008

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EXAMINER

MCKANE, ELIZABETH L

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

02/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/659,354	<b>Applicant(s)</b> PERLOV ET AL.	
	<b>Examiner</b> Leigh McKane	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 November 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,9-15,20-23 and 26-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,9-15,20-23 and 26-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 November 2007 has been entered.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 9-11, 20-22, and 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bithell (US 4,348,357) in view of Chollet et al. (WO 9835708).

With respect to claims 1-3, 9-11, 20-22, 26, and 27, Bithell teaches a method for sterilizing an item within a chamber **11** having a door and electrodes **16**. See Figure 1. The method of Bithell includes the steps of disposing an item within the chamber and performing a plurality of sterilizing cycles. Each cycle includes the step of pumping the atmosphere from the chamber until the atmosphere of the chamber has a pressure of less than one torr (Figure 2,  $t_1$ ,  $t_4$ ,  $t_7$ ,  $t_9$ ; col.4, lines 3-10 and lines 20-26). This pressure (line **51** in Figure 2) is disclosed to be 0.05 Torr. Next a reactant gas is injected at approximately the same time an electrical discharge is generated (col.4, lines 10-16). During this time, the generated radicals diffuse within the

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chamber. Once the upper pressure limit (1-10 Torr) is reached by the generated discharge, the electrical discharge is broken if the article being sterilized is heat sensitive. See col.5, lines 32-39. Then the cycle is repeated. Bithell does not teach that the reactive gas is water vapor and ozone.

Chollet et al. discloses a method of sterilizing surgical instruments with plasma, wherein the articles are first impregnated with a mixture of ozone and water vapor. The ozone is generated from oxygen **52** in an ozonizer **58**. After a period of time a vacuum is imposed on the chamber holding the articles to remove the majority of the gas from the instruments. Finally, a plasma is generated from the ozone and water vapor remaining in the articles. Chollet et al. specifically teaches that the ozone/water vapor mixture is chosen because it produces free radicals. Chollet et al. further discloses that the combination of the ozone/water vapor mixture with plasma exhibits a synergistic sterilization effect. See page 9, lines 27-31. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to employ the ozone/water vapor gas mixture of Chollet et al. for the oxygen of Bithell, since Chollet et al. discloses that this particular gas mixture achieves a sterilization synergy.

With respect to the number of cycles to be repeated, Bithell discloses that this can be readily achieved through experimentation for the particular treatment parameters. See col.5, lines 56-61.

As to claim 28, Bithell is silent with respect to a biological air filter to filter entering air. Chollet et al., however discloses a bacterial filter **96** which filters all air entering into sterilization chamber **10**. As a bacterial filter would prevent recontamination of a sterilized article, it would have been an obvious modification to the system of Bithell.

With respect to claim 29, Bithell fails to teach an ozone destruction filter. Chollet et al. evidences an ozone destruction filter **38** in the gas exit of the sterilization chamber. As this filter is disclosed by Chollet et al. to convert exiting ozone into oxygen before releasing the gas to the atmosphere (page 5, lines 3-6), it would have been an obvious modification to the apparatus of Bithell.

As to claims 30-33, it is deemed obvious to positions the electrodes of Bithell in any arrangement capable of producing the desired plasma. A suitable arrangement would have been readily determinable by one of ordinary skill in the art.

With respect to claim 31, one would have found it obvious to provide a second door for the exiting, sterile item. Such is known in the art and would have been obvious to the skilled practitioner.

4. Claims 4 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bithell and Chollet et al. as applied to claims 1 and 20 above, and further in view of Karlson (US 5,868,999).

The combination *supra* produces the water vapor by bubbling the ozone gas through a reservoir of water **72**. The ozone is not passed over the water. However, Karlson discloses that an ozone/water vapor mixture may be produced by using a bubbler (Figure 4B) like that of Chollet et al. *or* by passing the ozone gas over a reservoir of water (Figure 4A). See col.14, line 60 to col.15, line 24. As Karlson demonstrates the equivalence of the two methods, it would have been obvious to substitute one for the other in the combination of Bithell with Chollet et al..

5. Claims 12 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bithell and Chollet et al. as applied to claims 1 and 20 above, and further in view of Masuda (US 5,120,512).

The combination of Bithell with Chollet et al. fails to teach recycling at least a part of ozone which was added to the chamber. Masuda discloses a method and apparatus for ozone sterilization wherein ozone gas leaving the chamber is recycled back to the ozone generator for restoring or increasing the ozone content of the gas. See claim 2. It would have been obvious to do the same in the combination of Bithell with Chollet, in order to increase the ozone concentration of the gas exiting the generator.

6. Claims 13-15 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bithell and Chollet et al. as applied to claims 1 and 20 above, and further in view of Protic (US 2004/0022673).

Chollet et al. seems to indicate the desirability of augmenting the quantity of free radicals in the chamber. See page 9, lines 31-35. Nevertheless, Protic teaches in a plasma sterilization method that “during the production of plasma, additional oxygen electrons or free radicals may be introduced into the sterilisation chamber or area to be sterilized.” See paragraph [0047]. Furthermore, Protic discloses that any lumen-containing devices within the load being sterilized can be connected to the supply or exhaust ports, such that the sterilant and free radicals are drawn through the lumen. The free radicals may be injected into the chamber by a plasma generator. As this augmenting of free radicals and circulation of the sterilant through the lumen merely increases the overall biocidal action of the gas plasma (paragraph [0038]), it would have been an obvious modification to the invention of Bithell with Chollet et al..

7. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bithell and Chollet et al. as applied to claim 33 above, and further in view of Jacob (US 5,302,343).

While the combination of Bithell and Chollet et al. is silent with respect to a region of zero field gradient within the chamber, this particular embodiment is disclosed by Jacob in a plasma sterilization chamber. Jacob teaches a central region of zero field gradient which is permits an article to be sterilized at substantially lower process temperatures. See col.9, lines 50-57. It would have been obvious to one of ordinary skill in the art to arrange electrodes within the chamber of the combination in a suitable manner in order to achieve a region of zero field gradient in order to achieve sterilization at lower process temperatures.

#### ***Response to Arguments***

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Leigh McKane/  
Primary Examiner, Art Unit  
1797**

elm  
18 February 2008